

## II. REMARKS

Reconsideration of the present application as amended, and in view of the following remarks, is respectfully requested.

Claims 1, 2, 4-11, 13-16, 20-24, 26-27, 29-38 and 40-45 are currently pending. Claims 1, 8, 20, 26, and 44 have been amended. Claims 3, 12, 17-19, 25 and 28 have been canceled. Claim 39 has been previously withdrawn. It is respectfully submitted that no new matter has been added by virtue of the present amendment.

### A. Rejection under 35 U.S.C. § 112

Claim 35 was rejected under 35 U.S.C. §112, second paragraph, on the grounds that the term “rubber-like polymer” does not set out the meets and bounds of the claim.

In response, it is respectfully submitted that the meets and bounds of the term, “rubber-like synthetic polymer” are known by those of skill in the art. This is evidenced by, e.g. U.S. Patent 5,240,711 to Hille et al. (cited in the present Office Action) which states at column 3, line 25, “[e]xamples of polymers are rubber, rubber-like synthetic homo-, co- or blockpolymers, polyacrylic esters and copolymers thereof, polyurethanes and silicones.”

Claim 44 was rejected on the grounds that the limitation, “softening ester” lacks sufficient antecedent basis in claim 23. In response, claim 44 has been amended without prejudice to recite “softening agent” in place of “softening ester” in order to be in proper antecedent form.

Accordingly, Applicant respectfully requests reconsideration and withdrawal the 35 U.S.C. §112, second paragraph rejections.

**B. Rejection under 35 U.S.C. § 103 over Kogan et al.**

Claims 1-16, 20-38 and 40-45 were rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over U.S. Patent No. 4,910,205 (Kogan et al.). Applicant respectfully traverses this rejection.

The Office Action contends that “it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a transdermal device to deliver loratadine to treat allergic conditions as disclosed by [Kogan] and adjust the dose to deliver a specific desired plasma profile according to the patient’s need, motivated by the teachings of [Kogan] that the dose may be varied depending on the size and age of the patient, and may also depend upon the severity of the condition being treated, with reasonable expectation of having a transdermal delivery device that delivers loratadine at the desired levels and treats allergic conditions effectively.”

In response to this rejection, the Examiner is directed to independent claims 1, 8, 20, and 26 which recite, in part, “ . . . *a plasma level of loratadine at steady state from about 1 to about 3 ng/ml.*”. Applicant notes that the Office Action has acknowledged that Kogan et al. do not teach the specific delivery profile of the claimed invention. Further, although Kogan et al. are directed to a composition for the transdermal delivery of loratadine, Applicant contends that Kogan et al. fail to disclose 1.) any clinical trials, 2.) any indications that the loratadine transdermal systems disclosed were ever administered to humans, and 3.) any teaching or suggestion of any desired pharmacokinetic parameters. Accordingly, Applicant respectfully contends that Kogan et al. do not teach or suggest the plasma levels of loratadine at steady state from about 1 to about 3 ng/ml, as recited in the claims.

In addition, the Office Action fails to provide any motivation to obtain the steady state plasma level of from about 1 to about 3 ng/ml, as recited in the claims. Applicant notes that the factual question of motivation is material to patentability, and cannot be resolved on subjective belief and unknown authority. The Examiner must explain reasons why one of ordinary skill in the art would have been motivated to select

references and to combine them to render the claimed invention obvious. See *In Re Lee*, 61 USPQ2d 1430, (Fed. Cir. 2002). It is respectfully submitted that the Examiner's motivation to modify Kogan et al. to arrive at Applicant's claimed plasma levels of loratadine at steady state from about 1 to about 3 ng/ml are based on subjective belief and unknown authority. This is evident as the Office Action has not provided any objective authority (e.g., a secondary reference) in combination with Kogan et al. which would provide motivation to one skilled in the art to arrive at the claimed steady state plasma levels of loratadine.

Applicant further submits that the Office Action relies on impermissible hindsight to reconstruct the invention as claimed based on the knowledge provided by the present application.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1-16, 20-38 and 40-45.

**C. Rejection under 35 U.S.C. § 103 over Aslanian et al. in view of Miranda et al.**

Claims 1-16, 20-38 and 40-45 were rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over U.S. Patent No. 6,103,735 (Aslanian et al.) in view of U.S. Patent No. 5,091,186 (Miranda et al.). Applicant respectfully traverses this rejection.

In response, the Examiner is directed to independent claims 1 and 8, which recite, in part:

Claim 1: "A method ... comprising ... maintaining said transdermal delivery system in contact with the skin of said patient **for at least 3 days**, ... maintaining a therapeutic blood level until the end of at least the **three-day dosing interval**, said transdermal delivery device maintaining a plasma level of loratadine at steady state from about **1 to about 3 ng/ml**" (Emphasis added)

Claim 8: "A method ... comprising ... maintaining said transdermal delivery system in contact with the skin of the patient **for at least 5 days** ... maintaining a therapeutic blood level until the end of at least the **five-day dosing interval**, said

transdermal delivery device maintaining a plasma level of loratadine at steady state from about **1 to about 3 ng/ml** (Emphasis added)

The Examiner acknowledged that Aslanian et al. do not teach the delivery profile of claims 1 and 8, and relies on Miranda et al. in an attempt to cure this deficiency. Miranda et al. describe at column 6, lines 20-21, a system that “enables biphasic delivery **over an approximately 24-hour dosing period ...**” (Emphasis Added). Miranda et al. further describes at column 7, lines 37-39, that “[t]he patch may thus be removed and replaced **every day** at about the same time.” (Emphasis Added). Applicant respectfully contends that Miranda et al. neither teach nor suggest maintaining the transdermal delivery system in contact with the skin of a patient for at least 3 or 5 days, as claimed in claims 1 and 8 respectively, nor maintaining a therapeutic blood level until the end of at least the 3 or 5 day dosing interval, as also claimed in claims 1 and 8 respectively. Miranda et al. do not provide any indication that the device described therein is suitable for at least a 3 or 5 day dosing interval, nor does it provide the motivation to modify Aslanian et al. to achieve such a results. Therefore, even assuming arguendo that one modifies Aslanian et al. with Miranda et al. as alleged in the Office Action, at best one would result in a transdermal system of loratadine suitable for 24 hours.

Further, Aslanian et al. and Miranda et al. do not exemplify loratadine transdermal devices and there is no indication in either Aslanian et al. or Miranda et al. of loratadine devices having the instantly claimed characteristics. Accordingly, neither Aslanian et al. nor Miranda et al. disclose any clinical trials, any indications that loratadine transdermal systems were ever administered to humans, and any teaching or suggestion of any desired pharmacokinetic parameters for loratadine. Therefore, Applicant contends Aslanian et al. and Miranda et al., either alone or in combination, fail to teach or suggest the plasma levels of loratadine at steady state from about 1 to about 3 ng/ml, as recited in the claims.

The Examiner is also directed to independent composition claim 20 which recites, in part, “a transdermal delivery system comprising loratadine or a pharmaceutically acceptable salt thereof which provides ... a plasma level of loratadine at steady-state

from about **1 to about 3 ng/ml.**”. As asserted above, the cited references neither teach nor suggest a transdermal delivery system which provides this pharmacokinetic parameter. Therefore, the plasma levels recited in independent claim 20 are neither taught nor suggested by Aslanian et al. taken in combination with Miranda et al.

The Examiner is also directed to independent composition claim 26 which recites, in part, “a transdermal delivery system ... maintaining a therapeutic blood level until the end of at least the **five-day dosing interval**, which maintains a plasma level of loratadine at steady-state from about **1 to about 3 ng/ml.** As asserted above, the cited references neither teach nor suggest a transdermal delivery system which provides these pharmacokinetic parameters. Therefore, the particular dosing interval and plasma level recited in independent claim 26 are neither taught nor suggested by Aslanian et al. taken in combination with Miranda et al..

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1-16, 20-38 and 40-45.

**D. Rejection under 35 U.S.C. § 103 over Kogan et al. in view of Hille**

Claims 37, 38, 44 and 45 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kogan et al. in view of U.S. Patent No. 5,240,711 (Hille et al.). Applicant respectfully traverses this rejection.

The Office Action acknowledges that Kogan et al. do not disclose the specific solvents and softening agents claimed in the present invention, but asserts it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Kogan et al. and Hille et al. in order to cure this deficiency.

Kogan et al. are directed to a pharmaceutical composition for the transdermal delivery of loratadine. In contrast, Hille et al. are directed to a buprenorphine transdermal delivery device. Applicant contends that Hille et al. do not teach or suggest a transdermal delivery device utilizing any active agent other than buprenorphine.

Accordingly, one skilled in the art would not modify Kogan et al. with Hille et al. in order to formulate a loratadine transdermal delivery system.

Further, Hille et al. do not teach or suggest the plasma levels of loratadine, as discussed above, with respect to independent claim 20 which are incorporated into dependent claims 37, 38, 44 and 45. Therefore, even assuming *arguendo* that the cited art were to be combined in the matter proposed in the Office Action, one skilled in the art would still not arrive at the invention as claimed in claims 37, 38, 44 and 45.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 37, 38, 44 and 45.

**E. Rejection under 35 U.S.C. § 103 over Aslanian et al. and Miranda et al. in view of Hille et al.**

Claims 37, 38, 44 and 45 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Aslanian et al. in view of Miranda et al. as applied to claims 1-16, 20-38, and 40-45, and further in view of Hille et al. Applicant respectfully traverses this rejection.

As discussed above with respect to claim 20 (from which claims 37, 38, 44 and 44 depend), one skilled in the art would not be motivated to combine the teachings of Aslanian et al. and Miranda et al. as proposed in the Office Action. Therefore, Applicant respectfully contends the Office Action's rejection based on the combination of Aslanian et al. and Miranda et al., further in view of Hille et al. should be withdrawn.

Further, neither Aslanian et al., Miranda et al., nor Hille et al. teach or suggest plasma levels of loratadine, as discussed above, with respect to independent claim 20 which are incorporated into dependent claims 37, 38, 44 and 45. Therefore, even assuming *arguendo* that Aslanian et al., Miranda et al. and Hille et al. were combined in the matter proposed in the Office Action, one skilled in the art would still not arrive at the

invention as claimed in claims 37, 38, 44 and 45. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 37, 38, 44 and 45.



**III. CONCLUSION**

In view of the foregoing, Applicant believes that the above-referenced rejections have been obviated and respectfully request that all rejections be withdrawn. Applicant believes that all claims are now in condition for allowance. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance prosecution of the present application. An early and favorable action is earnestly solicited.

Respectfully submitted,  
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